

File No. Q-11013/6/2015-eGov

FTS: 3035352

**Subject: Drafting of Legislation on Electronic Health Data privacy, confidentiality and security- reg**

This relates to the drafting of legislation on Electronic Health Data privacy, confidentiality and security. Two meetings of Legal Sub Group had been held on 13<sup>th</sup> January, 2015 and 15<sup>th</sup> April 2015 under the Chairmanship of AS&DG (CGHS) to discuss the Health Data Privacy and Security in India.

2. In the Second meeting of Legal Sub Group, it was decided to request the selected institutes of repute having requisite domain expertise, for the expression of interest (EOI) for drafting of the proposed Act. In this regard following four institutes were identified:

- IIT- Kharagpur
- National Law School of India University- Bangalore
- Indian Law Institute- New Delhi
- National Academy of Legal Studies and Research- Hyderabad

3. Ministry has received EOI from all the Four Institutes and a meeting of Legal Sub-group under EMR/EHR Standards Committee was held under the chairmanship of Shri K.B. Agarwal, AS(eGov.), MoHFW on 14th October, 2015 to review the EOIs received from the identified legal institutes for drafting the proposed legislation for Electronic Health Data Privacy & Security.

4. In the meeting, it was decided to invite four institutes to MoHFW for presentation exhibiting their understanding of the scope of work, proposed approach & methodology, previous project experience, resource strength etc. before the Legal Sub-group.

5. Another meeting of Legal Sub-group under EMR/EHR Standards Committee was held under the chairmanship of Shri K.B. Agarwal, AS (eGov.), MoHFW on 1<sup>st</sup> December, 2015 to evaluate the presentations made by the identified legal institutes for drafting the proposed legislation.

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6. As per the decisions taken in the meeting (p.376/C), NALSAR University of Law, Hyderabad and National Law School of India University, Bangalore were shortlisted for inviting financial quotes and were asked to submit financial quotes by 18.01.2015. (P 382-383/C).

7. Financial quotes from both the legal institutes have been received by the Ministry. NALSAR University of Law, Hyderabad has proposed financial quote to the tune of Rs. 51,38,200/- (placed at 'F/A') and financial quotes submitted by National Law School of India University, Bangalore are Rs. 27,00,000/- (placed at 'F/B').

8. Since the financial quotes from both the institutes have been received file is submitted for further decisions/ directions please.

आशीष शर्मा  
(आशीष शर्मा)  
19/1/16  
सहायक अनुभाग अधिकारी (ई गवर्नेंस)

सहायक निदेशक (ई गवर्नेंस)

अमित कुमार  
19/1/16

डॉक्टर सचिव (ई. गव.)

सौम्या  
19/01/16

निर्देश (ई. गव.)

It was decided in the last meeting of Legal Sub-group that the selection of the Institute will be based on lower financial bid out of the two bids submitted. Therefore we may award the work of Drafting the Legislation on Electronic Health Data Privacy & Security in India to "National Law School of India University, Bangalore" for an expenditure of Rs 27,00,000/=.

A | Submitted for approval please

जि.एम.  
19/1/16  
Director (eGov)

JS/JS

① above may kindly be considered approved.

AS/BA

AS/CA

Secretary

Pl. examine & submit.

UB/FV

27.1.16

27/1

M/o Health & F.W.  
I.F.D.I  
Dy./F.T.No.  
Date: 19/1/16

Min. of Health & F.W.  
A.S. & P.A.S. O.I.  
F.TS No. 103/15  
Date: 27/1/16



-43/N-

FTS No.3035352

Integrated Finance Division

This is regarding drafting of Legislation on Electronic Health Data privacy, confidentiality and security.

2. The Division has stated that in the second meeting of Legal Sub Group, it was decided to request the selected institutes of repute having requisite domain expertise for the Expression of Interest (Eoi) for drafting of the proposed Act. In this regard, four Institutes have been identified (refer p.41/n).

3. The Ministry has received Eoi from all the four Institutes. The said Institutes were invited by the Ministry for presentation exhibiting their understanding of the scope of work, proposed approach & methodology, previous project experience, resource strength etc. After evaluating the presentation, two Institutes viz., NALSAR University of Law, Hyderabad and National Law School of India University, Bangalore were shortlisted for inviting financial quotes.

4. Financial quotes have been received from these two Institutes. NALSAR University of Law, Hyderabad proposed financial quote of Rs.51,38,200/- (F/A) and financial quote of National Law School of India University, Bangalore is Rs.27,00,000/- (F/B). The Division has sought concurrence of IFD for awarding the working of drafting of Legislation on Electronic Health Data privacy, confidentiality and security to National Law School of India University, Bangalore for Rs.27,00,000/-.

5. In this regard, it may be observed that as per GFR 151, Limited Tender Enquiry may be adopted when the estimated value of the goods to be procured is upto Rs.25.00 lakh. However, purchase through Limited Tender Enquiry may be adopted even where the estimated value of procurement is more than Rs.25.00 lakh in certain circumstances, as elaborated in the extracts of GFR at F/X.

6. The Division may be advised to examine the proposal in the light of GFR 151 and ensure that the proposal is in accordance with GFR provisions under reference.

Submitted please.

(Thomas Mathew)  
US (F-V)  
01.02.2016

Director (IFD)

US (F-V)

Dir (JA)

- The decisions were taken by the Committee formed after due approval of Secretary (HFW) [page 7/n]. Committee has decided to seek EOI from Govt legal institutes of repute. Four Institutes were selected after due deliberation by the said Legal Group formed.
- (ii) In the 3rd meeting, only two Institutes were short-listed after the detailed presentation given by these four Institutes and [page 376/c]. Financial Quote were obtained from these Institutes.
- (iii) The above process is not actually a case of Limited Tender Enquiry as such, as we have not estimated the cost of services to be obtained from these Institutes.

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More-over these Institutes are reputed and have been involved by other departments / Ministries for joining ~~these~~ the similar nature of work.

- (iv) A moU with the selected Institute will be signed for proceeding any payment for rendering services and the progress will be monitored by Legal Subgroup formed.

~~The~~ The selected Institute is of Govt. of Karnataka and not ~~an~~ a Private Institute. The quoted price is mainly for man months involved for drafting the proposed legislation for EHR data Privacy & security and Institute charges.

In view of above clarifications, IFD may ~~be~~ consider for concurrence. In the 50th meeting dt. 31.12.16, the matter was discussed and <sup>top</sup> as per mom, the work is to be taken up on ~~part~~ party and to be completed by June 30/16

F/X<sub>1</sub>

Sham  
4/2/16  
Director (eGov)

JS (eGov)

4/2/16

AS (14/SA)

4/2/16

(F)

439  
M/O H.O. 3 PM  
I.F.D. 3035352  
Dy. I.F.D. 3035352  
Date: 4/2/16



-45/N-

FTS No.3035352

Integrated Finance Division

This is regarding drafting of Legislation on Electronic Health Data privacy, confidentiality and security.

2. IFD examined the case vide p.43/n and sought certain clarifications. The Division has now furnished the requisite clarifications vide p.43-44/n.

3. In this connection, it may be recalled that in the second meeting of Legal Sub Group, it was decided to request the selected institutes of repute having requisite domain expertise for the Expression of Interest (Eoi) for drafting of the proposed Act. In this regard, four Institutes have been identified (refer p.41/n).

4. The Ministry has received Eoi from all the four Institutes. The said Institutes were invited by the Ministry for presentation exhibiting their understanding of the scope of work, proposed approach & methodology, previous project experience, resource strength etc. After evaluating the presentation, two Institutes viz., NALSAR University of Law, Hyderabad and National Law School of India University, Bangalore were shortlisted for inviting financial quotes.

5. In the third meeting of the Legal Sub Group, only two Institutes were shortlisted, after the detailed presentation given by the four Institutes (p.376/c). As regards shortlisting of two Institutes, it has been clarified that these two Institutes are reputed and have been involved by other Departments/Ministries for framing the similar nature of work.

6. It has been stated that MoU with selected Institutes will be signed for proceeding any payment for rendering services and the progress will be monitored by Legal Sub Group.

7. Financial quotes have been now received from these two Institutes. NALSAR University of Law, Hyderabad proposed financial quote of Rs.51,38,200/- (F/A) and financial quote of National Law School of India University, Bangalore is Rs.27,00,000/- (F/B). The Division has sought concurrence of IFD for awarding the work of drafting of Legislation on Electronic Health Data privacy, confidentiality and security to National Law School of India University, Bangalore for Rs.27,00,000/- (B).

8. It is also mentioned that the quoted price is mainly for man months involved for drafting the proposal legislation for EHR data privacy & security and Institute charges. The Division has also stated that in the Senior Officers' Meeting on 31.12.2015, the matter was discussed and as per the Minutes of the meeting, the work is to be taken up on top priority and to be completed by June 2016 (F/X).

9. In view of the facts and circumstances explained by the Division, IFD may concur in the proposal of the Division for awarding the work of drafting of Legislation on Electronic Health Data privacy, confidentiality and security to National Law School of India University, Bangalore for Rs.27,00,000/- *subject to approval of Secretary (HFW).*

(Thomas Mathew)  
US (F-V)  
05.02.2016

lf. clarification given on page

43-44/n. Para

9 for consideration  
H.

Director (IFD)

AS 2/FA

Dir/IFD (C/1)

US (F/V)

Min. of Health & F.W.

A.S. & FA'S Office

FTS No. 3035352

Date: 5.2.16

Note No. #1

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File No. Q-11013/6/2015-eGov

FTS: 3035352

**Subject:** Drafting of Legislation on Electronic Health Data privacy, confidentiality and security- reg

This relates to the drafting of legislation on Electronic Health Data privacy, confidentiality and security. Two meetings of Legal Sub Group had been held on 13<sup>th</sup> January, 2015 and 15<sup>th</sup> April 2015 under the Chairmanship of AS&DG (CGHS) to discuss the Health Data Privacy and Security in India.

2. In the Second meeting of Legal Sub Group, it was decided to request the selected institutes of repute having requisite domain expertise, for the expression of interest (EOI) for drafting of the proposed Act. In this regard following four institutes were identified:

- IIT- Kharagpur
- National Law School of India University- Bangalore
- Indian Law Institute- New Delhi
- National Academy of Legal Studies and Research- Hyderabad

3. The Ministry has received EOI from all the four Institutes. The said Institutes were invited by the Ministry for presentation exhibiting their understanding of the scope of work, proposed approach & methodology, previous project experience, resource strength etc. After evaluating the presentation, two Institutes viz., NALSAR University of Law, Hyderabad and National Law School of India University, Bangalore were shortlisted for inviting financial quotes. (P-376/C)

4. Financial quotes from both the legal institutes have been received by the Ministry. NALSAR University of Law, Hyderabad has proposed financial quote to the tune of Rs. 51,38,200/- (placed at 'F/A') and financial quotes submitted by National Law School of India University, Bangalore are Rs. 27,00,000/- (placed at 'F/B').

5. The concurrence of IFD has been received for awarding the work of drafting of Legislation on Electronic Health Data privacy, confidentiality and security to National Law School of India University, Bangalore for Rs.27,00,000/-.

6. File is submitted for approval of Secretary (HFW) for awarding the work of drafting of Legislation on Electronic Health Data privacy, confidentiality and security to National Law School of India University, Bangalore.

प्रतिष्ठान  
जितेंद्र अरोड़ा  
निदेशक (ई गवर्नेंस)

संयुक्त सचिव (ई गवर्नेंस)

सुनील शर्मा  
1/2

रवि सक्लिन (के.पी.ए.)

सचिव

वे जी अ

9/20

रवि सक्लिन  
9/1/16

अप. सक्लिन (के.पी.ए.)

सुनील शर्मा  
10/2/16  
निदेशक (ई गवर्नेंस)

JS(SS)

AD/leat

US/leat

10/2

Letter to be issued today

10/1/16



File No.Q-11013/6/2015-eGov

FTS No: 81876

**Subject: Approval of Draft Act for setting up of "National Digital Health Authority of India (NDHAI)" –reg**

This is regarding the Draft Act prepared by Ministry of Health & Family Welfare (MoHFW) for setting up of "National Digital Health Authority of India (NDHAI)".

2. In order to address the needs identified & delineated for standards, regulation, data privacy & security etc. in Indian eHealth ecosystem so as to achieve an orderly development and to gain effective & efficient results thereof, MoHFW decided to set up a nodal body in form of an "Authority" through an Act of parliament. Accordingly, a concept note in this regard was drafted by the Legal Sub-group under EHR Standards Committee of MoHFW and was consulted thoroughly with different stakeholders. Thereafter with approval of Hon'ble HFM, the concept note was put in public domain for soliciting suggestions/comments from general public. A national level consultation was also held on 4<sup>th</sup> April 2016 to discuss the concept note and thereafter it was finalised for further perusal.

3. Further, for drafting the Act for setting up the envisaged Authority, MoHFW mandated the task to National Law School of India University (NLSIU), Bengaluru in Feb, 2016. The draft Act for setting up the Authority by name "National Digital Health Authority of India (NDHAI)" has now been finalised after a number of rounds of discussions & deliberations with various stakeholders over the past few months. The stakeholders consulted for this purpose were drawn from divergent groups such as health service provider, medical professional, health informatics professional, industry association, legal experts etc. and other Ministries/Departments/Organisations such MeitY, UIDAI etc.

4. The key sections of the draft Act are regarding:

- Confidentiality, privacy, ownership of health data
  - o Rights to health data owner (i.e. Patient)
  - o Norms to be followed by health services providers/health information exchanges in regard to data privacy & security
- Establishment of National Digital Health Authority of India, its roles & power
- Recognition of Health Information Exchanges (HIEs) by NDHAI
- Operational guidelines and mandatory key manning for HIEs
- Issue of standardization, storage & transmission of data
- Nature of punishment (civil or criminal) etc., for data breach
- Setting up of Adjudicating Authority(ies)
  - o To penalise for data privacy & security breach
- Setting up of Appellate Tribunal

A brief note highlighting salient features of the Draft Act is placed at F/A.

5. It may also be noted that the National Health Policy (NHP) 2017 (copy enclosed at F/B) having recognised the integral role of technology (eHealth,

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in health, Cloud, Internet of things, wearables, etc.) in the healthcare delivery, also outlines setting up a National Digital Health Authority (NDHA) to regulate, develop and deploy digital health across the continuum of care. The Policy aims at an integrated health information system which serves the needs of all stakeholders and improves efficiency, transparency, and citizen experience. Therefore significance and role of NDHA emerges quite imperative and critical for overall development of Indian eHealth ecosystem in an orderly manner.

6. Now, as decided in the meeting held on 24<sup>th</sup> March 2017 under the chairmanship of AS&DG(CGHS) ( Minutes of meeting at F/C), it is proposed to put the Draft Act in public domain for a period of atleast one month for soliciting suggestions/comments from general public. Thereafter the suggestions/comments received would be analysed and appropriately addressed through modifications, as required, in the Draft Act. Further the work for preparation of Bill in coordination with Ministry of Law will be undertaken.

7. Accordingly, approval of Hon'ble HFM is solicited for putting the "Draft Act for setting up of NDHA" in public domain.

Submitted for approval of Hon'ble HFM please.

*Jitendra Arora*  
(Jitendra Arora)  
Director (eHealth)

JS(SS)

JS(LA)

*Pl. brief me about Act in person.*

*A*  
*18/5.*

*DA/CJM.*

*VS (elw)*



File No.Q-18015/23/2017-eGov  
FTS No: 3105692

**Subject: Approval of Draft Act for setting up of "National Digital Health Authority of India (NDHAI)" -reg**

This is regarding the Draft Act prepared by Ministry of Health & Family Welfare (MoHFW) for setting up of "National Digital Health Authority of India (NDHAI)".

2. In Health Sector, both public and private sectors, a number of Health Information Systems have currently been implemented which collect and collate health/clinical data of patients/citizens on a large and diversified scale. As a result huge health/clinical data repositories are being created and made use of. More number of such health information systems continue to be developed and implemented adding to the volume of health data repositories on a continuous basis. Also the use/transfer/transactions of health data, especially in electronic format, is continually increasing. Under such a scenario, privacy, confidentiality and security of health data/information, which is personal and sensitive in nature must be addressed adequately.
3. It is mentioned that there is lack of a dedicated and comprehensive legislation/regulation catering to the privacy, security and confidentiality of health data/information. Though there are a number of legislations put in place but these are specific only to particular health conditions/circumstances such as for mental/physical illness, disability, communicable diseases etc. It is observed that the existing legislations in health domain cover some aspects of privacy & security specific only to the mandated/limited scope. As a result, an individual may face difficulty in getting recourse on a model of "single-window concept" in case of any breach of his/her health data/information.
4. For electronic data, the Information Technology Act, 2000 provides legal recognition to any transaction, which is done by electronic way or use of Internet. The issue of data protection (to a limited extent for health sector) has been addressed in Information Technology Amendment Act, 2008. It protects in general private information that is obtained by agencies by virtue of powers conferred under the Act.
5. As, the importance for placing a pertinent value on protecting the privacy, confidentiality, and security of citizens' health data and information had been delineated in the past at different platforms by stakeholder groups, the Legal Sub-group of EHR Standards Committee of MoHFW reviewed the prevailing situation. It was brought out by the Legal Sub-group that a number of pertinent aspects such as consent for data collection, purpose limitation, access to data, correction, other rights to data owner, norms/guidelines for data sharing/exchange, provisions of exact penalty/offences/liability & remedy, security etc. are lacking under the existing legislations.
6. The need for statute specifically covering data privacy & security aspects in a comprehensive manner in Health Sector emerges more imperative in the context of promotion & adoption of e-Health on a large scale through establishment of pan-India Integrated Health Information System and EHR System including setting up of Health Information Exchanges under Digital India Programme.
7. In order to address the needs identified & delineated for regulation, data privacy & security etc. in Indian eHealth ecosystem so as to achieve an orderly development and to gain effective & efficient results thereof, MoHFW decided to set up a nodal body in form of an "Authority" through an Act of parliament. Accordingly, a concept note in this regard was drafted by the Legal Sub-group under EHR Standards Committee of MoHFW and was consulted thoroughly with different stakeholders. Thereafter with approval of Hon'ble HFM, the concept note was put in public domain for soliciting suggestions/comments from general public. A national level consultation was also held on 4<sup>th</sup> April 2016 to discuss the concept note and thereafter it was finalised for further perusal.

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8. Further, Ministry has given assurances in Parliament in respect of two Lok Sabha Unstarred questions No. 5250 dated 24.04.2015 and No. 1639 25.11.2016. The Current status furnished to the Committee on Government Assurances is as below(F/X):

**(i) LOK SABHA USQ No.5250:**

*"A concept note of NeHA was prepared and National consultation was held on 4<sup>th</sup> April, 2016; Establishment of National e-Health Authority (NeHA) is clubbed with Health Data Privacy & Security Act. Recently, a draft of legislation prepared by National Law School of India University (NLSIU), Bengaluru has been discussed on 24<sup>th</sup> March 2017. Key suggestions made by participants and legal experts have been noted and the draft is being revised accordingly."*

**(ii) LOK SABHA USQ No. 1639:**

*"The work of drafting the proposed legislation for Health Data Privacy & Security Act, was awarded to National Law School of India University (NLSIU), Bengaluru. 1<sup>st</sup> draft of the legislation was prepared by NLSIU & submitted to MoHFW. 2<sup>nd</sup> Draft of the legislation is ready and is under discussion."*

Recently AS(H) has taken a review meeting on 18<sup>th</sup> May, 2017 to review the assurance of the Ministry. He has directed all the divisions to fulfil all the assurances at the earliest.

9. For drafting the Act for setting up the envisaged Authority, MoHFW mandated the task to National Law School of India University (NLSIU), Bengaluru in Feb, 2016. The draft Act for setting up the **Central Authority** by name "**National Digital Health Authority of India (NDHAI)**" has now been finalised after a number of rounds of discussions & deliberations with various stakeholders over the past few months. The stakeholders consulted for this purpose were drawn from divergent groups such as health service provider, medical professional, health informatics professional, industry association, legal experts etc. and other Ministries/Departments/Organisations such MeitY, UIDAI etc.

10. The key sections of the draft Act are regarding:

- Confidentiality, privacy, ownership of health data
  - Rights to health data owner (i.e. Patient)
  - Norms to be followed by health services providers/health information exchanges in regard to data privacy & security
- Establishment of National Digital Health Authority of India, its roles & power
- Recognition of Health Information Exchanges (HIEs) by NDHAI
- Operational guidelines and mandatory key manning for HIEs
- Standardization, storage & transmission of data (rules to be formulated later by NDHAI)
- Nature of punishment (civil or criminal depending on case) etc., for data breach
- Setting up of Adjudicating Authority(ies)
  - To penalise for data privacy & security breach
- Setting up of Appellate Tribunal

*A brief note highlighting salient features of the Draft Act is placed at F/A.*

11. It may also be noted that the **National Health Policy (NHP) 2017** (copy enclosed at F/B) having recognised the integral role of technology (eHealth, mHealth, Cloud, Internet of things, wearables, etc.) in the healthcare delivery, also outlines setting up a National Digital Health Authority (NDHA) to regulate, develop and deploy digital health across the continuum of care. The Policy aims at an integrated health information system which serves the needs of all stake-holders and improves efficiency, transparency, and citizen experience. Therefore significance and role of NDHA emerges quite imperative and critical for overall development of Indian eHealth ecosystem in an orderly manner.



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**Subject: Approval of Draft Act for setting up of "National Digital Health Authority of India (NDHAI)" -reg**

12. In the meeting held on 24<sup>th</sup> March 2017 under the chairmanship of AS&DG it was proposed to put the Draft Act in public domain by 31<sup>st</sup> May 2017, for a period of at least one month for soliciting suggestions/comments from general public. Thereafter the suggestions/comments received would be analysed and appropriately addressed through modifications, as required, in the Draft Act. Further the work for preparation of Bill in coordination with Ministry of Law will be undertaken. (FC)

Hon'ble MoS (AP) taken a review meeting of eHealth on 15.05.2017 and directed that the deadline for 31.05.17 to put the Draft Act in public domain by 31<sup>st</sup> May 2017, should be adhered.

Accordingly, approval of Hon'ble HFM is solicited for putting the "Draft Act for setting up of NDHAI" in public domain.

*Jitendra Arora*  
22/5/17  
(Jitendra Arora)  
Director (eHealth)

*JS(LA) on tour*

*AS&DG*

*Secy (HFW)*

*Vatol*  
23/5/17

*MOS (AP)*

*27.5.17.*

*U. J. Singh*  
24/5

*HFM*

Office of the Minister of H&FW  
COMPUTERISED  
FTS No. 3105692  
Date 29/5/17

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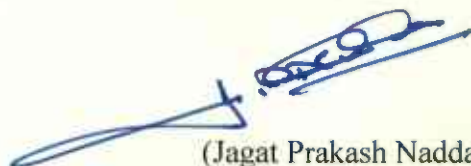


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-12-

Ref. notings from p.9/n regarding setting up of National Digital Health Authority of India.

2. Secretary (H&FW) may please discuss the issue with me.



(Jagat Prakash Nadda)  
Union Minister of Health & F.W.  
June 6, 2017

Secretary (H&FW)

This was discussed. We may bring up this issue when a presentation on all aspects of IT interventions is made.

*Jh*  
26/7

*BSLH*  
*Q*  
31/7

*Dir (e-H)*

*US (H)*

*SL*  
11/8/2017

*Jh*  
1/8/17

AD (ehealth)

**Note No. #2**

29/09/2017 2:53 PM

AMIT KUMAR-AD  
(AD)**Note No. #3****Subject: Approval of Draft Act for "Digital Healthcare Data Privacy, Confidentiality & Security" –reg**

Reference note from page 9-12/ ante regarding the Draft Act prepared by Ministry of Health & Family Welfare (MoHFW) for addressing and ensuring privacy, confidentiality and security of digital healthcare data by setting up of an institutional framework (consisting of National Digital Health Authority of India- NDHA, Adjudicating Authorities etc.), regulations & rules etc. and putting it in public domain for inviting comments.

2. It is submitted that, in Health Sector, both public and private sectors, a number of Digital Health Systems have currently been implemented which collect and collate health/clinical data of patients/citizens on a large and diversified scale. As a result huge health/clinical data repositories are being created and made use of. More number of such health information systems continue to be developed and implemented adding to the volume of health data repositories on a continuous basis. Also the use/transfer/transactions of health data, especially in electronic format, is continually increasing. Under such a scenario, privacy, confidentiality and security of health data/information, which is personal and sensitive in nature must be addressed adequately.

3. It is mentioned that at present there is no dedicated and comprehensive legislation/regulation specially catering to the privacy, security and confidentiality of sensitive health data/information. Though there are a number of legislations put in place but these are specific only to particular health conditions/circumstances such as for mental/physical illness, disability, communicable diseases etc. It is observed that the existing legislations in health domain cover some aspects of privacy & security specific only to the mandated/limited scope. As a result, an individual may face difficulty in getting recourse on a model of "single-window concept" in case of any breach of his/her health data/information.

4. The need for statute specifically covering data privacy & security aspects in a comprehensive manner in Health Sector emerges more imperative in the context of promotion & adoption of Digital Health on a large scale through establishment of pan-



**India Integrated Health Information System and Electronic Health Record (EHR) System including setting up of Health Information Exchanges (for transmission and sharing of EHRs of citizens) under Digital India Programme.**

5. In order to address the needs identified & delineated for regulation, data privacy & security etc. in Indian Digital Health ecosystem so as to achieve an orderly development and to gain effective & efficient results thereof, MoHFW planned to set up a nodal body in form of an “Authority” through an Act of parliament. Accordingly, a concept note in this regard was drafted and was consulted thoroughly with different stakeholders. Thereafter with approval of Hon’ble HFM, the concept note was put in public domain for soliciting suggestions/comments from general public. A national level consultation was also held on 4<sup>th</sup> April 2016 to discuss the concept note and thereafter it was finalized for further perusal.

6. Further, Ministry has given assurances in Parliament in respect of two Lok-Sabha Unstarred questions No. 5250 dated 24.04.2015 and No. 1639 dated 25.11.2016 for bringing in Act for setting up of NDHA for Digital Healthcare Data Privacy, Confidentiality & Security. Accordingly Ministry started working on preparation of a comprehensive draft legislation in this direction to explicitly render protection to an individual in terms of privacy, confidentiality and security covering the key aspects such as ‘ownership’ of ‘digital health data’, ‘health data standardization in collection, storage, exchange’ and ‘framework to provide civil and criminal remedies for data breach’.

7. For drafting the Act, MoHFW mandated the task to National Law School of India University (NLSIU), Bengaluru in Feb, 2016. After discussions & deliberations with MoHFW and various stakeholders and taking inputs from them, NLSIU prepared and submitted the draft (i.e. NDHAI Act) accordingly [vide letter dated 15.09.2017](#) based upon the last discussion held in MoHFW. The draft submitted by NLSIU proposes setting up of Digital Health Authority at central level only i.e. NDHAI.

8. Thereafter, MoHFW had further deliberations with National Health Systems Resource Centre (NHSRC) and also Legislative department (Ministry of Law) on the draft Act submitted by NLSIU. During the deliberations, in view of the administrative and constitutional issues involved it was suggested that the proposed institutional framework set-up should also have state-level digital health authorities in addition to national level digital health authority for ensuring engagement of the states on this critical issue of health data privacy & security and better addressal of digital health standardizations across health service providers and health information exchanges. Accordingly the draft submitted by NLSIU has been modified. The modified draft is placed on file. The key sections of the draft Act (i.e. **Digital Healthcare Data Privacy, Confidentiality & Security Act**) are regarding:

- ❑ Confidentiality, privacy, ownership of health data- rights to health data owner (i.e. Patient); Norms to be followed by health services providers/health information exchanges in regard to data privacy & security
- ❑ Establishment of National Digital Health Authority of India (NDHA) and State Digital Health Authorities (SDHA), their organisational structures, roles & power
- ❑ Setting up of Health Information Exchange(s) (HIEs) by central government
- ❑ Operational guidelines and mandatory key manning for HIEs
- ❑ Standardization, storage & transmission of data (rules to be formulated later by NDHA & SDHA)
- ❑ Nature of punishment (civil or criminal depending on case) etc., for data breach
- ❑ Setting up of Adjudicating Authority(ies) at State levels- To address complaints of data breach against a clinical establishment or any & penalise accordingly
- ❑ Setting up of Adjudicating Authority at Central - To address complaints of data breach against a health information exchange or State Digital Health Authority or the National Digital Health Authority & penalise accordingly

*A brief note highlighting salient features of the Draft Act is placed at [F/A](#).*

8. In this context, it is mentioned that the file seeking approval of Hon'ble HFM for putting the Draft Act in public domain was submitted on 22.5.2017. However, it was decided that this issue may be brought up when a presentation on all aspects of health IT interventions is made (**Page 12/n**). During the review held under the chairmanship of Hon'ble HFM on **19.08.17** the draft Act was discussed and Hon'ble HFM desired that the matter should also be discussed with Ministry of Electronics & Information Technology (MeitY) to find out whether an independent Act for Health Department is required or it shall be subsumed within the Act being prepared by the MeitY. **(MoM at Page 175 / c)**

9. In this regard , it is stated that the data protection act is being drafted by MeitY in consultation with UIDAI with reference to the development of a landmark Judgment passed by Hon'ble Supreme court on Aadhar Act on (2017, August-24 ). However, this data protection act is currently at the conceptual level and consultations are currently being organized to identify "key data protection issues" and to suggest a draft data protection Bill accordingly. The need to have an independent Act for Health Domain has therefore been examined as advised by Hon'ble HFM and based on the examination, it is mentioned that:

- i. There are two global approaches to protect individual right of privacy viz., (i) through a legislation which would be overarching all aspects of privacy. UK's data protection Act or some countries that have an explicit provision of privacy included in to their

constitution are good instances of this approach; (ii) by having a sectoral specific law - which would address sector specific issues. *In India universal formulation was attempted by inserting provisions in Information and Technology Act, which are not felt to be sufficient to protect individual privacy to the desired level. Therefore Aadhaar legislation, further addresses the issue separately.*

- ii. Health data is globally accepted to be a 'sensitive data' which deserves to be protected more than other forms of 'personal data'. Therefore the contention is to have a dedicated/specialized legal framework.
- iii. Nonetheless, a health sector focused Act is imperative given the typical nature of operational issues involved given "care-provider" centric model of delivery. In health sector violation of privacy involving highly sensitive data can take place in a number of areas like unnecessary collection of data, purpose of collecting data not specified, refusal to provide records upon request by client, disclosure of information without consent, inadequate notification to a patient of a data breach, use for public health analysis etc. Therefore patients must feel at ease while sharing private & health information and medical history when availing healthcare services.

10. It is also submitted that , recognizing the integral role of technology i.e. eHealth, mHealth, cloud, Internet of things IOT, wearables etc. in the health care delivery , the **National Health Policy 2017** also advocates setting up of a National Digital Health Authority (NDHA) to regulate, develop and deploy digital health across the continuum of care, which is approved by Cabinet.

11. In view of above, it is submitted that the requirement of protecting digital data privacy & security aspects in a comprehensive manner in Health sector can be fulfilled only by a statute specifically dedicated to health sector. Hence an independent Act for data privacy & security in digital Health Domain is still required to be perused despite a data protection act would be co-exist. Therefore the present draft legislation being piloted by MoHFW, which would not conflict or overlap any attempt (in whichever stage) by the MeitY.

12. As per the process, the Draft Act on **Digital Healthcare Data Privacy, Confidentiality & Security** is to be put in public domain (for a period of at least one month) and to be shared with States/UTs for soliciting suggestions/comments. Also public consultation will be held. Thereafter, the suggestions/comments received would be analyzed and appropriately addressed through modifications/ changes, as required, in the Draft Act and also would be aligned with the overall national level data privacy framework being draft by MeitY. After finalization of the Act, the work for preparation of Bill in coordination with Ministry of Law will be undertaken.

A copy of the modified [draft act is placed on file and may be seen at pg.251/c](#)



*Accordingly, approval of Hon'ble HFM is solicited for putting the "Draft Act for Digital Healthcare Data Privacy, Confidentiality & Security" in public domain.*

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29/09/2017 6:36 PM

JITENDRA ARORA  
(DIR)

**Note No. #4**

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03/10/2017 2:42 PM

JITENDRA ARORA  
(DIR)

**Note No. #5**

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04/10/2017 12:31 PM

R K VATS  
(AS AND DG)

**Note No. #6**

HFM may like to take a presentation on this.

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07/10/2017 5:52 PM

C K MISHRA  
(SECRETARY)

**Note No. #7**

As advised by Hon'ble HFM, the undermentioned discussed this matter with JS (LA) today (2.11.2017). It is requested that this issue may be processed as per the discussion and submitted for consideration of Hon'ble HFM.

(Ritesh Chauhan)  
PS to Hon'ble HFM

JS (LA)

02/11/2017 6:28 PM

JAGAT PRAKASH NADDA(HFM)  
(HFM)

**Note No. #8**

04/11/2017 11:09 AM

LAV AGARWAL  
(JS)

**Note No. #9**

Reference above :

As discussed, a table, showing the suggestions given by PS to HFM office (on the draft put up) along with the remarks/ observations ( brief comments) of the division has been prepared and placed on file ([pg.282 /c](#))

The revised draft Act on "**Digital Information Security in Healthcare, Act (DISHA)**" incorporating above suggestions is placed on file at [pg.288/c](#).

Accordingly, approval of Hon'ble HFM is solicited for putting the Draft Act *in public domain*.



22/11/2017 5:48 PM

**JITENDRA ARORA**  
(DIR)

**Note No. #10**

As per the discussion with PS to Hon HFM , certain suggestions/modifications have been incorporated in the draft Act. The proposed Act is accordingly recirculated. It is submitted that the same may be examined and Act put up in public domain for comments.

New suggestions as and when obtained after putting the Act in public domain will help refine the draft further.

There is already a Parliament Assurance on the subject and we may need to initiate required necessary steps wrt finalisation of Act.

It will ensure providing required framework for implementing Electronic Health Standards in the country.

May be approved at Hon HFM level.



24/11/2017 4:56 PM

**LAV AGARWAL**  
(JS)

**Note No. #11**

During discussion on e-Pharmacy , Secy. desired that formal consultation should be held with MHA , MieTy as they are dealing with general issues of privacy and cyber security. Same holds here also.



11/12/2017 12:31 PM

**R K VATS**  
(AS AND DG)

**Note No. #12**

Let us write to concerned Ministry for their comments as directed by AS & DG.



15/12/2017 11:58 AM

**LAV AGARWAL**  
(JS)



**Note No. #13**

Draft letter to Miety and MHA is attached for approval and signature please.

21/12/2017 10:28 AM

S C RAJEEV  
(DIR)

**Note No. #14**

21/12/2017 11:20 AM

LAV AGARWAL  
(JS)

**Note No. #15**

22/12/2017 10:54 AM

D JEEVARAJ  
(PPS)

**Note No. #16**

25/12/2017 8:01 AM

S C RAJEEV  
(DIR)

**Note No. #17**

Reference- note above.

D.O letters were sent to Secretary, MHA and Secretary, MeitY seeking comments and suggestions on the draft act of these two Ministries before putting up the same in public domain for feedback. Since comments/suggestions have not been received from these two Ministries, it is proposed to send a reminder as per draft(DFA/3156950) put up for approval please.



03/01/2018 5:26 PM

S K PANI  
(US)

**Note No. #18**

03/01/2018 6:02 PM

S C RAJEEV  
(DIR)

**Note No. #19**



04/01/2018 3:16 PM

LAV AGARWAL  
(JS)

**Note No. #20**

08/01/2018 3:46 PM

D JEEVARAJ  
(PPS)

**Note No. #21**

09/01/2018 9:36 AM

S C RAJEEV  
(DIR)

**Note No. #22**



09/01/2018 9:48 AM

S K PANI  
(US)

**Note No. #23**

16/01/2018 10:02 AM

AMIT KUMAR-DD  
(DY.DIR)**Note No. #24**

16/01/2018 4:37 PM

HUNNY WADHWA  
(ASO)**Note No. #25**

19/01/2018 3:36 PM

AMIT KUMAR-DD  
(DY.DIR)**Note No. #26**

19/01/2018 3:46 PM

HUNNY WADHWA  
(ASO)**Note No. #27**

**Subject: Approval of Draft "Digital Information Security in Healthcare, Act (DISHA)" for putting it in public domain for inviting comments-reg**

This is regarding putting up the Draft "**Digital Information Security in Healthcare, Act (DISHA)**" in public domain for comments.



Earlier, the file was submitted for approval of Hon'ble HFM for putting the draft act in public domain for inviting comments. On this, Secreary(HFW) directed that "*formal consultation should be held with MHA and MeitY as they are dealing with general issues of privacy and cyber security*".

Ministry has sent the draft act to MHA and MeitY vide D.O. letter dated [21st December, 2017](#) and vide subsequent reminder letter dated [16th January, 2018](#) requesting their comments / suggestions on the draft act. So far, no communication has been received from MHA and MeitY in this regard.

It is therefore proposed that file may be submitted for seeking approval of Hon'ble HFM for putting the draft act in public domain for inviting comments. New suggestions as and when obtained after putting the Act in public domain will help refine the draft further.



09/02/2018 3:00 PM

AMIT KUMAR-DD  
(DY.DIR)

#### Note No. #28

In reference to above it is to submit that comments of MHA has been received and place at [page 360](#) in correspondence. The same may be perused pl. The comments of Meity are yet to be received . A reminder have also been sent. It is therefore proposed that file may be submitted for seeking **approval of Hon'ble HFM for putting the draft act in public domain for inviting comments** . The Suggestions of public and comments of MHA , Meity and other related ministry/dept will be incorporated accordingly.

12/02/2018 7:40 PM

S C RAJEEV  
(DIR)

#### Note No. #29

The draft Act has been made in consultation with National law School , Bangalore and NHSRC duly involving subject experts also.

This issue was discussed in Secy H meeting with Secy IT wherein it was decided that while Meity will come with an overarching Act on data privacy , Ministries like Health need to come up with their separate Acts on Digital Health data issues. Certain comments as obtained through PS to HFM have already been incorporated in the draft also.

As was earlier endorsed by AS & DG , we had written to MHA and Meity and response after regular follow up has only come from MHA. Their comments can be incorporated as part of updation after obtaining public comments on the issue.

Present proposal is also part of our Assurance and is already badly delayed.  
Permission may be given to put up the draft in Public domain for obtaining comments  
as part of wider consultation.  
approval at Hon HFM level may be given pl.

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14/02/2018 2:21 PM

LAV AGARWAL  
(JS)

**Note No. #30**

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22/02/2018 4:27 PM

R K VATS  
(AS AND DG)

**Note No. #31**

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22/02/2018 7:05 PM

PREETI SUDAN  
(SECRETARY)

**Note No. #32**

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24/02/2018 11:32 AM

R K VATS  
(AS AND DG)

**Note No. #33**

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26/02/2018 8:34 PM

ANUPRIYA SINGH PATEL  
(MOS)

**Note No. #34**



01/03/2018 10:38 AM

JAGAT PRAKASH NADDA(HFM)  
(HFM)

**Note No. #35**



06/03/2018 4:56 PM

ANUPRIYA SINGH PATEL  
(MOS)

**Note No. #36**



06/03/2018 5:18 PM

PREETI SUDAN  
(SECRETARY)

**Note No. #37**



08/03/2018 8:33 PM

R K VATS  
(AS AND DG)

**Note No. #38**



11/03/2018 11:08 AM

LAV AGARWAL  
(JS)

**Note No. #39**

13/03/2018 9:37 AM

S C RAJEEV  
(DIR)

**Note No. #40**

13/03/2018 10:37 AM

AMIT KUMAR-DD  
(DY.DIR)

**Note No. #41**

Reference Notes above:

Hon'ble HFM has approved for placing the draft "**Digital Information Security in Healthcare, Act (DISHA)**" in public domain for comments. In this regard, two drafts has been prepared for the following:

1. Notice for placing the draft act on Ministry's Website for public comments.
2. A DO letter to Principal Secretaries of all States/UTs and to all JSs in the Ministry for their comments.

For approval Please

A green checkmark followed by the word "Sign" in a cursive, handwritten-style font.

15/03/2018 5:05 PM

HUNNY WADHWA  
(ASO)

**Note No. #42**





15/03/2018 5:32 PM

AMIT KUMAR-DD  
(DY.DIR)

**Note No. #43**

for approval of draft and signature of letter at sr. No 2 above please.

18/03/2018 2:19 PM

S C RAJEEV  
(DIR)

**Note No. #44**



19/03/2018 9:56 PM

LAV AGARWAL  
(JS)

**Note No. #45**

20/03/2018 5:17 PM

S C RAJEEV  
(DIR)

**Note No. #46**

draft act has been put up in public domain at ministry's website on 21.03.2018.

Letters have been sent to all the states for comments. pls upload o/c.

05/04/2018 12:17 PM

AMIT KUMAR-DD  
(DY.DIR)

**Note No. #47**

11/05/2018 4:53 PM

HUNNY WADHWA  
(ASO)

**Note No. #48**

18/05/2018 5:19 PM

AMIT KUMAR-DD  
(DY.DIR)

**Note No. #49**

This is regarding the Draft Act prepared by Ministry of Health & Family Welfare (MoHFW) for setting up of “**Digital Information Security in Healthcare, Act (DISHA)**” to regulate, develop standards and strategize & deploy digital health across the continuum of care.

2. The draft “**Digital Information Security in Healthcare, Act (DISHA)**” has been made in consultation with National Law School, Bangalore and NHSRC involving subject experts. Hon'ble HFM has approved for placing the draft in public domain for comments. The draft act was put in public domain at Ministry's website on [21.03.2018](#) for a period of one month.

3. It is also informed that the letters were also sent to the Principal Secretaries of all the States/UTs for their comments. States/ UTs have not sent any inputs/comments on this act till date.

4. Further, Ministry has sent the draft act to MHA and MeitY vide D.O. letter dated [21st December, 2017](#) and subsequent reminder letter dated [16th January, 2018](#) requesting their comments / suggestions on the draft act. So far, no communication has been received from MHA and MeitY in this regard.

5. So far, **70 comments** / suggestions have been received from different organizations/individuals through emails and by post. The comments/suggestions received from various these organizations/individuals have been compiled and examined by eHealth Team. The compiled comments along with action point/remarks may be seen at [p.368-490/cor.](#)

6. However, to incorporate the received suggestions in the draft act appropriately, it is proposed that a committee with legal experts, healthcare -IT experts, doctors, etc may be constituted for following activities:

- i. to examine the comments for its legal validity
- ii. to check whether the suggestions are aligned with the objective of the draft act
- iii. to incorporate the suggestions in the appropriate sections of the draft act

Submitted for consideration and further orders please.



18/05/2018 5:38 PM

S K PANI  
(US)

#### Note No. #50

In reference of above it is to mentioned that as per para 7 of of MOM dated 15/1/18 held under co chairmanship of Secy (H) and Secy(IT) copy attached below, "Secretary MeitY appraised that his Ministry has come-up with Data Protection Act which is currently placed in public domain and would create baseline for protection of citizen data. However, he also informed that domain specific specialized regulations or act would come from concerned ministries and suggested that Digital Health Data Privacy Act developed by MoHFW may be shared with MeitY for alignment with the provisions of Data Protection Act".

In this respect , Ministry has sent the draft act to MHA and MeitY vide D.O. letter dated 21st December, 2017 and subsequent reminder letter dated 16th January, 2018 requesting their comments / suggestions on the draft act. The comments has been received from MeitY in this regard, vide letter dated 17/5/2018, copy placed at page 491-495.

In above respect it is to mentioned that recently MeitY has also drafted "White paper on Data protection framework in India". The undersigned was asked to examine this framework thoroughly to find out whether an independent Act for Health Department is required or it shall be absorbed within the Act being prepared by the MeitY to avoid multiple act on similar issues. In this respect it is to mentioned that the 'Substantive Part' of DISHA act broadly covers the followings aspect:

- **Confidentiality, privacy, ownership of health data**
- **Issue of standardization, storage, transmission of data & Health Information Exchange**
- **Establishment of Regulatory Bodies as National eHealth**

**Authority (NeHA) at national level & State eHealth Authority (SeHA) at State level, its roles and power**

- **Nature of punishment (civil or criminal) etc., for data breach**
- **Setting up of Adjudicating Authority & Appellate Tribunal**

While going through the drafted "White paper on Data protection framework of Meity, it is observed that White paper on Data Protection in India developed by MeitY has broadly covered all aspect of the Data Privacy, security and protection in general and in principle the need for having separate Data protection act for Health need to be looked into.

4. Further, MOHFW emphasises on building inter-operability amongst various Health IT Systems to achieve a uniform standard-based system for creation and maintenance of Electronic Health Records (EHRs) of citizens. However to fulfill this alignment of DISHA and proposed Data Protection framework developed by MeitY is essential and must be ensured.

As directed a DFA from Secy(H) to Secy(IT) is also prepared and is placed for approval please.

 **MoM held on 15 January 2018-sect H -Secy IT.pdf**

28/05/2018 7:05 PM

**S C RAJEEV  
(DIR)**

**Note No. #51**

Draft DO letter may be approved pl.



31/05/2018 9:52 AM

**LAV AGARWAL  
(JS)**

**Note No. #52**

 **3105692.pdf**

01/06/2018 11:39 AM

**SANJEEVA KUMAR  
(AS)**

**Note No. #53**

Kindly see the endorsement of Incharge Secy H wherein it was directed to put the file to Secy H after return from leave.  
For favour of approval accordingly pl.





01/06/2018 11:57 AM

LAV AGARWAL  
(JS)

**Note No. #54**

04/06/2018 10:59 AM

PREETI SUDAN  
(SECRETARY)

**Note No. #55**

04/06/2018 11:52 AM

A HARIDAS  
(PPS)

**Note No. #56**

05/06/2018 11:25 AM

B NEELA MOHANA RAO  
(PERSONAL ASSISTANT)

**Note No. #57**



05/06/2018 11:31 AM

LAV AGARWAL  
(JS)

**Note No. #58**

05/06/2018 6:55 PM

S C RAJEEV  
(DIR)

**Note No. #59**



06/06/2018 9:52 AM

S K PANI  
(US)

**Note No. #60**

Response from MeitY has been received , pls put up.

20/08/2018 3:51 PM

AMIT KUMAR-DD  
(DY.DIR)

**Note No. #61**

PUC is a communication received from Shri Ajay Sawhney, Secretary, MeitY referring to the D.O. letter dated 04th June 2018 from Secretary (H) requesting MeitY to examine the draft DISHA legislation and advise whether Ministry of Health need to come up with a separate Act on Digital Health or that MeitY shall come up with a comprehensive Data Protection Framework offering domain specific flexibility to define their own standards in proposed framework to avoid multiple data protection legislation.

2. Shri Sawhney has apprised that with the objective to ensure growth of the digital economy while keeping personal data of citizens secure and protected, a Committee of Experts on Data Protection has been constituted under the Chairmanship of Justice B.N. Krishna, Former Judge, Supreme Court of India. The committee comprises of members from Government, Academia and Industry, with the aim of studying and identifying key data protection issues and recommending methods for addressing them.

3. It is also mentioned in the PUC that the committee released a white paper on 27th November 2017 to solicit public comments on what shape a data protection law could take. With respect to the comments received, committee is presently at an advanced stage of finalization of its report. The committee has been requested to submit a report on "Data Protection Framework" as expeditiously as possible.

4. With respect to concerns regarding overlap between DISHA and the proposed framework, Shri Sawhney has informed that **draft Data Protection**

**Framework includes clear role for Sectoral Regulators who will be involved in sector specific guidelines and codes of practice.**

5. File is submitted for information and further guidance on this matter.

21/08/2018 2:58 PM

ASHISH SHARMA-II(EGOV)  
(ASO)

**Note No. #62**

 Digitally Signed

21/08/2018 3:46 PM

AMIT KUMAR-DD  
(DY.DIR)

**Note No. #63**

23/08/2018 10:17 AM

S C RAJEEV  
(DIR)

**Note No. #64**

Comments from MEITY are submitted for perusal and further n/a pl.

 Digitally Signed

26/08/2018 9:59 AM

LAV AGARWAL  
(JS)

**Note No. #65**

 Digitally Signed

27/08/2018 7:13 PM

SANJEEVA KUMAR  
(AS)

**Note No. #66**

Comments from Meity may be seen. As per above , we may have till Data Protection Framework is finalized by MEITY and role of sectors is delineated properly.

We may address MEITY accordingly for further course of action.



31/08/2018 2:26 PM

LAV AGARWAL  
(JS)

**Note No. #67**



07/09/2018 5:42 PM

SANJEEVA KUMAR  
(AS)

**Note No. #68**



10/09/2018 5:55 PM

PREETI SUDAN  
(SECRETARY)

**Note No. #69**



10/09/2018 5:56 PM

SANJEEVA KUMAR  
(AS)

**Note No. #70**

Pl. put up draft accordingly.



10/09/2018 6:21 PM

LAV AGARWAL  
(JS)



**Note No. #71**

14/09/2018 12:19 PM

**S C RAJEEV  
(DIR)****Note No. #72**

14/09/2018 12:34 PM

**S K PANI  
(US)****Note No. #73**

A draft letter has been prepared and is placed for approval please.

14/09/2018 5:17 PM

**ASHISH SHARMA-II(EGOV)  
(ASO)****Note No. #74**

As directed by JS(eHealth), a draft has been put up informing MeitY that Ministry of Health and Family Welfare shall put DISHA on hold till the notification of Data Protection Framework by MeitY. The role of Ministry of Health and Family Welfare, as laid under the Data Protection Framework, will be taken up after the notification to avoid any contradiction.

For approval please.



17/09/2018 10:58 AM

**AMIT KUMAR-DD  
(DY.DIR)****Note No. #75**

18/09/2018 6:57 PM

S C RAJEEV  
(DIR)

**Note No. #76**

pl. discuss draft.



21/09/2018 6:31 AM

LAV AGARWAL  
(JS)

**Note No. #77**

Pl modify dfa as discussed.

03/10/2018 5:28 PM

S C RAJEEV  
(DIR)

**Note No. #78**

As discussed, the Draft has been revised and submitted pls.



04/10/2018 11:11 AM

AMIT KUMAR-DD  
(DY.DIR)

**Note No. #79**

08/10/2018 1:17 PM

S C RAJEEV  
(DIR)

**Note No. #80**



11/10/2018 2:06 PM

LAV AGARWAL  
(JS)

**Note No. #81**

D.O. Letter has been signed and sent for issue.

17/10/2018 4:54 PM

**D JEEVARAJ**  
(PPS)

**Note No. #82**

25/10/2018 1:50 PM

**S C RAJEEV**  
(DIR)

**Note No. #83**

25/10/2018 2:11 PM

**S K PANI**  
(US)

**Note No. #84**

pls attached the letter signed by JS in the file.

29/10/2018 12:58 PM

**AMIT KUMAR-DD**  
(DY.DIR)

**Note No. #85**

29/10/2018 3:46 PM

**CHARU KHATTER**  
(EXECUTIVE ASSTT)

**Note No. #86**

06/12/2018 11:54 AM

ASHISH SHARMA-II(EGOV)  
(ASO)

**Note No. #87**

17/12/2018 4:49 PM

HUNNY WADHWA  
(ASO)

**Note No. #88**

06/02/2019 4:38 PM

ASHISH SHARMA-II(EGOV)  
(ASO)

**Note No. #89**

File discussed with AS(H) w.r.t. Cabinet Note being prepared.



07/02/2019 7:01 PM

SACHIN MITTAL  
(DIR)

**Note No. #90**

26/03/2019 10:09 AM

ASHISH SHARMA-II(EGOV)  
(ASO)

**Note No. #91**

28/03/2019 2:31 PM

HUNNY WADHWA  
(ASO)



**Note No. #92**

28/03/2019 2:54 PM

ASHISH SHARMA-II(EGOV)  
(ASO)**Note No. #93**

24/04/2019 3:53 PM

HUNNY WADHWA  
(ASO)**Note No. #94**

12/07/2019 10:31 AM

ASHISH SHARMA-II(EGOV)  
(ASO)**Note No. #95**

23/07/2019 1:38 PM

HUNNY WADHWA  
(ASO)**Note No. #96**

A D.O. letter from JS (eHealth) was sent to Secretary (MeitY) submitting that the report of the committee under the chairmanship of Justice B.N. Srikrishna, Former Judge Supreme Court of India has been submitted to MeitY and MeitY may outline the clear role of Ministry of Health and Family Welfare in respect of Data Protection Framework and for further directions, if any, on the draft of Digital Information Security in Healthcare Sector (DISHA) as proposed.

2. No response has been received from MeitY till date. Submitted for necessary direction please.

23/07/2019 3:06 PM

ASHISH SHARMA-II(EGOV)  
(ASO)

**Note No. #97**

26/07/2019 5:43 PM

**JOGINDER PAL  
(US)****Note No. #98**

06/10/2020 10:51 AM

**HUNNY WADHWA  
(ASO)****Note No. #99**

20/10/2020 3:55 PM

**AMITA VAID  
(SO)****Note No. #100**

We may propose to send another d.o reminder. Pl put up accordingly with draft d.o. letter

20/10/2020 4:03 PM

**JOGINDER PAL  
(US)**

File No: Z-18015/3/2018-eGov-Part(1)  
Government of India  
Ministry of Health and Family Welfare  
e-Health Section

Nirman Bhawan, New Delhi  
Dated 30<sup>th</sup> January, 2018

**Subject:** Minutes of the meeting held under the Joint Chairmanship of Secretary(HFW) & Secretary (MeitY) on 15<sup>th</sup> January 2018, in Nirman Bhavan, New Delhi.

The undersigned is directed to enclose herewith the Minutes of the meeting held under the Joint Chairmanship of Secretary(HFW) & Secretary (MeitY) on 15<sup>th</sup> January 2018 in Nirman Bhavan, New Delhi for information and necessary action.

**Encl.:** Minutes of meeting.



(S.K. Pani)

Under Secretary to the Government of India

To,

1. Secretary, MeitY, Electronics Niketan, CGO Complex, New Delhi
2. CEO, NeGD, MeitY, Electronics Niketan, CGO Complex, New Delhi
3. Addl. Secy. (Health), MoHFW
4. AS&DG (CGHS), MoHFW
5. AS&MD (NHM), MoHFW
6. Joint Secretary(VG), MoHFW
7. Joint Secretary (eHealth), MoHFW
8. Joint Secretary(AS), MoHFW
9. Director (eHealth) MoHFW
10. Sr. Technical Director, NIC
11. Additional Director, CHI, NIHFW, MoHFW
12. Deputy Director (eHealth), MoHFW

**Copy to:-**

Sr. PPS to Secretary(HFW), Nirman Bhawan, New Delhi

**Ministry of Health & Family Welfare (MoHFW)**  
**eHealth Division**  
**Government of India**  
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**Minutes of the Meeting**

**Subject: Minutes of meeting held under the Joint Chairmanship of Secretary Health & Secretary IT on 15<sup>th</sup> January 2018, at Room No. 155 A, Nirman Bhavan, New Delhi.**

A meeting regarding IT related issues and Computerization was held on 15<sup>th</sup> January 2018 at 5:30PM in Ministry of Health & Family Welfare, New Delhi. The meeting was co-chaired by Secretary Health & Family welfare and Secretary MeitY. The list of participants in enclosed in annexure-1.

2. **Secretary, Health & Family Welfare** Ms. Preeti Sudan welcomed the participants and has emphasized that IT has a great role to play in healthcare and Ministry of Health & Family Welfare has taken many initiatives in this regard. She, however also pointed out that most of these initiatives are in pieces and it is difficult to sometime form a bigger picture out of it and suggested that MeitY should help MoHFW to integrate these IT systems so that data is made available for program and policy management.

3. **Secretary, MeitY**, Shri Ajay Prakash Sawhney mentioned that MeitY has come-up with a major plan for creating Trillion Dollar digital economy in India and a report in this regard has been published which has recommended deeper penetration of IT in many areas including health. He suggested that MoHFW can prioritize the areas where IT interventions are required and MeitY would provide all required support. He gave examples of larger systems such as MCTS, CGHS being created and managed by MeitY and appraised that similar support would continue in all major upcoming areas from MeitY to MoHFW.

4. Joint Secretary (e-Gov), Shri Lav Agarwal made a detailed presentation on the current status of IT in healthcare, the challenges faced, determinants of successful nation-wide health information programs, proposed vision for e-health architecture and required e-health ecosystem. Various issues were discussed during the course of presentation i.e. current IT infrastructure, lack of integration among health IT system, standards creation and compliance, certification of IT systems on standards and legal framework for protecting privacy and confidentiality of healthcare data.

5. It was suggested that some states have done better in terms of HIS and Telemedicine implementations. These needs to be studied, documented and some of these may be taken-up for scale-up. It was also suggested that limited use of Tele-medicine/ Tele-consultation needs to be studied and a strategic plan for proper utilization of Tele-medicine services needs to be chalked out.

6. **Use of Hospital Information Systems (HIS) /EHR ( Electronic Health Record)** systems by states for generation of clinical data was discussed in great details and it was agreed that electronic health record of the patient is critical for generating population analytics. In this regard issues related to procurement of IT systems was brought for discussion and Secretary H&FW suggested that MoHFW's notified EHR standards may be shared with MeitY for identification, certification and listing of IT systems which are compliant with these standards. These certified systems may be empanelled and listed in GEM for procurement by states and central government and the same can be coordinated by Meity. She also mentioned that GEM may also be addressed to undertake the listing of softwares which are as per standards on their portal. C-DAC Pune which has been entrusted with the task of EHR standards implementation may work with GeM in this regard.

7. **Healthcare data privacy and security** in addition to use of Aadhaar for identification purposes in healthcare, methods of data storage, cloud-based models, repositories and exchange were also discussed in detail. Secretary MeitY appraised that his ministry has come-up with Data Protection Act which is currently placed in public domain and would create baseline for protection of citizen data. However, he also informed that domain specific specialized regulations or act would come from concerned ministries and suggested that Digital Health Data Privacy Act developed by MoHFW may be shared with MeitY for alignment with the provisions of Data Protection Act.

8. **Secretary H&FW** suggested that MoHFW has some major upcoming programs and some of these require robust IT intervention. **While working on the issues as identified above, she has prioritized following five areas for immediate attention for with respect to use of IT:**

- I. **Comprehensive Primary Care Services and NCD Screening:** A set of services are being planned to be rolled-out under comprehensive primary health care strategy of MoHFW. Some of the components of this are already computerized such as MCTS/RCH Portal and ANMOL and for some other components new software systems are being developed such as NCD screening. We need to integrate these so that continuity of care is maintained and longitudinal record for patients is created . She proposed that to begin with the program should be launched in 115 Aspirational districts (along with already identified districts by NHM) and then same be rolled out pan India and requested Meity to coordinate and support the initiative.
- II. **Tele-medicine nodes:** She proposed that Meity shall support launching telemedicine (including tele diagnostics, teleconsultation) pan India connecting all remote PHCs. To begin with these shall be launched in 115 identified Aspirational districts.
- III. **e-Learning in Healthcare:** MoHFW supports various training programs. Some of these are routine trainings however some are specialized training programs. We need to convert

most of these into e-learning modules. Swayam Portal of HRD Ministry can be studied for this purpose.

- IV. **National Health Protection Scheme:** Proposed NHPS scheme would require a robust application during implementation. She requested MeitY to take this as a high priority task and help prepare an application for the same duly analyzing the existing application which are being used by states presently. It was agreed that MeitY would help MoHFW towards identification of suitable software systems for NHPS and MeitY would assign an officer at Joint Secretary/Director level to coordinate with MoHFW in this regard.
- V. **Dashboard:** There is an urgent need to build monitoring dashboard for MoHFW where the ministry is able to see the performance of states on various health indicators and can rank states or even districts based on their performance. NITI Aayog as well as state of Andhra Pradesh are using similar Dashboard and she proposed it accordingly to be prioritized.

It was decided that a detailed plan of action on each of these would be worked out by MeitY and shared with Min. of H&FW.

Meeting ended with vote of thanks to Chair.

#### Annexure – I

S.No	Name	Designation /Org.
1	Ms. Preeti Sudan	Secretary H&FW
2	Sh. Ajay Prakash Sawhney	Secretary, MeitY
3	Sh. Sanjeev Gupta	CEO, NeGD
4	Sh. Sanjeeva Kumar	Addl. Secy. (Health)
5	Dr RK Vats	AS&DG (CGHS)
6	Sh. Manoj Jhalani	AS&MD (NHM)
7	Ms. Vandana Gurnani	Joint Secretary
8	Sh. Lav Agarwal	Joint Secretary (eHealth), MoHFW
9	Sh Alok Saxena	Joint Secretary
10	Sh SC Rajeev	Director (eHealth) MoHFW



11	Sh. Sunil Kumar	Sr. Technical Director, NIC
12	Sh. Ankit Tripathi	Additional Director ,CHI,
13	Sh SK Pani	Under Secretary(eHealth)
14	Sh Amit Kumar	Deputy Director (eHealth)
15	Sh Amit Mishra ,	Consultant. MOHFW
16	Sh Gurucharan Singh	Consultant eHealth, MoHFW
17	Sh Suresh S.	Consultant eHealth, MoHFW
18	Sh. Vijay Kumar	Consultant eHealth, MoHFW
19	Sh. Abhishek Chnadra	Consultant eHealth, MoHFW
20	Sh. Himanshu Satija	McKinsey & Company
21	Ms Ipshita Mandal	McKinsey & Company

----- End of Document -----

**• Setting up of Adjudicating Authority & Appellate Tribunal**

While going through the drafted "White paper on Data protection framework of MeitY, it is observed that White paper on Data Protection in India developed by MeitY has broadly covered all aspect of the Data Privacy, security and protection in general and in principle the need for having separate Data protection act for Health need to be looked into.

4. Further, MOHFW emphasises on building inter-operability amongst various Health IT Systems to achieve a uniform standard-based system for creation and maintenance of Electronic Health Records (EHRs) of citizens. However to fulfill this alignment of DISHA and proposed Data Protection framework developed by MeitY is essential and must be ensured.

As directed a DFA from Secy(H) to Secy(IT) is also prepared and is placed for approval please.


28/05/2018 7:05 PM

S C RAJEEV  
(DIR)

Draft DO letter may be approved pl.

31/05/2018 9:52 AM

LAV AGARWAL  
(JS)

 Digitally Signed

for kind approval of Secy (HFW)

AS(H)

31/5

Secretary (HFW)

P. put up before Ms. Preeti Sudan, Secretary  
after her return from leave.

AS(H)

Arundha  
31/5